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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nicolau et al.

Application No.: 10/069,414

Filed: February 25, 2002

For: *Agents For The Enhanced Oxygen  
Delivery In Mammals*

Examiner: To Be Assigned

Art Unit: To Be Assigned

Attorney Docket No.: GMX-003.01

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on: July 22, 2002.

  
Daniel Murray

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**UNDER 37 CFR § 1.97 (b)(3)**

Commissioner for Patents  
Washington, DC 20231

Sir:

In compliance with the requirements of 37 C.F.R. §§ 1.56 and 1.97(b)(3), submitted herewith on Form PTO-1449 is a list of publications known to the Applicants and/or Applicants' agent. A copy of each publication is also submitted herewith. Applicants respectfully request that the Examiner consider the listed publications and indicate that each was considered by making appropriate notations on the enclosed Form PTO-1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that the cited documents are material or constitute "prior art." If the Examiner applies the listed documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law

regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of claims over the listed documents, should one or more of the referenced documents be applied against claims of the present application or of related applications.

Pursuant to 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. However, the Commissioner is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Account, No. 06-1448**.

Date: July 22, 2002

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Patent Group

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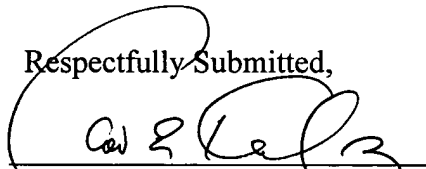
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Respectfully Submitted,

  
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Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
*(Use several sheets if necessary)*

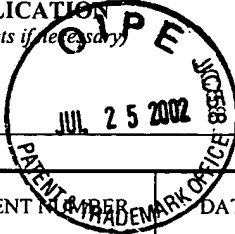
Docket Number (Optional)  
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Group Art Unit

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	US 4,588,394	05/13/86	Schulte et al.	604	9
	AB	US 4,681,560	07/21/87	Schulte et al.	604	9
	AC	US 4,699,926	10/13/87	Abraham et al.	514	563
	AD	US 4,731,473	03/15/88	Abraham et al.	562	464
	AE	US 4,731,381	03/15/88	Abraham et al.	514	571
	AF	US 4,751,244	06/14/88	Abraham et al.	514	563
	AG	US 4,887,995	12/19/89	Abraham et al.	604	4
	AH	US 4,921,997	05/01/90	Lalezari et al.	560	34
	AI	US 5,110,909	05/05/92	Dellacherie et al.	530	385
	AJ	US 5,079,337	01/07/92	Leonard et al.	530	385
	AK	US 5,296,466	03/22/94	Kilbourn et al.	514	6
	AL	US 5,344,393	09/06/94	Roth et al.	604	4
	AM	US 5,428,007	06/27/95	Fisher et al.	514	6
	AN	US 5,432,191	07/11/95	Abraham et al.	514	421
	AO	US 5,451,205	09/19/95	Roth et al.	604	6
	AP	US 5,599,974	02/04/97	Abraham et al.	562	463
	AQ	US 5,612,207	03/18/97	Nicolau et al.	435	173.6
	AR	US 5,731,454	03/24/98	Abraham et al.	560	43
	AS	US 5,872,282	02/16/99	Abraham et al.	562	458
	AT	US 5,927,283	07/27/99	Abraham et al.	128	898

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	AU	WO 92/20335	11/26/92	PCT			X
	AV	WO 92/20368	11/26/92	PCT			X
	AW	WO 92/20369	11/26/92	PCT			X
	AX	WO 95/03068	02/02/95	PCT			X
	AY	WO 97/31935	09/04/97	PCT		Abstract on the 1 <sup>st</sup> page	
	AZ	WO 96/01840	01/25/96	PCT			X

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BA	WO 96/18372	06/30/96	PCT				X
BB	WO 97/42819	11/20/97	PCT				X
BC	WO 98/39358	09/11/98	PCT				X
BD	WO 98/39359	09/11/98	PCT				X
BE	EP 0 338 916 A1	10/25/89	European Patent Application			English Abstract	
BF	EP 0 452 055 A1	10/16/91	European Patent Application				X
BG	JP 0 430 0838	10/23/92	Japan			English Abstract	

**OTHER DOCUMENTS**
*(Including Author, Title, Date, Pertinent Pages Etc.)*

BH	Antonini et al.; "The Effect of Anions and Cations on the Oxygen Equilibrium of Human Hemoglobin", Proc. Alfred Benzon Symp. 4 <sup>th</sup> (25YHA4): 121-130, (1972)
BI	Abraham et al.; "Physiological and x-ray Studies of Potential Antisickling Agents", Proc. Natl. Acad. Sci. USA 80: 324-328, (January 1983)
BJ	Abraham et al.; "Design, Synthesis, and Testing of Potential Antisickling Agents. I. Halogenated Benzyloxy and Phenoxy Acids", J. Med. Chem. 25: 1015-1017, (1982)
BK	Balcerzak et al.; "Studies on the Ability of Stored Blood to Transport Oxygen in Vivo", Adv. Exp. Med. Biol. 28: 433-447, (1972)
BL	Bruggemann et al.; "Low-Oxygen-Affinity Red Cells Produced in a Large-Volume, Continuous-Flow Electroporation System", Transfusion 35(6): 478-486, (June 1995)
BM	Benesch and Benesch; "The Effect of Organic Phosphates From the Human Erythrocyte on the Allosteric Properties of Hemoglobin", Biochemical and Biophysical Research Communications, 26(2):162-167 (1967)
BN	Benesch and Benesch; "Intracellular Organic Phosphates as Regulators of Oxygen Release by Haemoglobin", Nature 221 : 618-622 (February 15, 1969)
BO	Currell et al.; "Synthetic Polyphosphates, and Phosphonocarboxylates as Allosteric Effectors of Hemoglobin", Phosphorus, Sulfur, and Silicon 51/52: 35-38, (1990)
BP	Dietrich et al.; "Anion Receptor Molecules. Synthesis and Some Anion Binding Properties of Macrocyclic Guanidinium Salts", J.C.S. Chem. Comm. 21: 905-968, (1978)
BQ	Dietrich et al.; "Anion Coordination Chemistry: Polyguanidinium Salts as Anion Complexones", Helvetica Chimica Acta 62(fasc.8) Nr. 280: 2763-2787 (1979)

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BR

Echavarren et al.; "Anion-Receptor Molecules: Synthesis of a Chiral and Functionalized Binding Subunit, a Bicyclic Guanidium Group Derived from L- or D-Asparagine", Helvetica Chimica Acta 71: 685-693, (1988)

BS

Echavarren et al.; "Chiral Recognition of Aromatic Carboxylate Anions by an Optically Active Abiotic Receptor Containing a Rigid Guanidinium Binding Subunit", J. Am. Chem. Soc. 111: 4994-4995, (1989)

BT

Fantl et al.; "Specifically Carboxymethylated Hemoglobin as an analogue of Carbamino Hemoglobin", The Journal of Biological Chemistry 26(15):12700-12712, (1987)

BU

Hirst et al.; "The Modification of Hemoglobin Affinity for Oxygen and Tumor Radiosensitivity by Antilipidemic Drugs", Radiation Research 112: 164-172, (1987)

BV

Kilgore et al.; "RSR13, A Synthetic Allosteric Modifier of Hemoglobin, Improves Myocardial Recovery Following Hypothermic Cardiopulmonary Bypass", Circulation 100(Suppl. II): II-351-II356, (1999)

BW

Lalezari et al.; "New Effectors of Human Hemoglobin: Structure and Function", Biochemistry 29: 1515-1523, (1990)

BX

Lalezari et al.; "LR16, A Compound With Potent Effects on the Oxygen Affinity of Hemoglobin, on Blood Cholesterol, and on Low Density Lipoprotein", Proc. Natl. Acad. Sci. USA 85: 6117-6121, (August 1988)

BY

Nadolny et al.; "Specific Interactions of the Allosteric Effector 2, 3-Bisphosphoglycerate with Human Hemoglobin- A Difference FTIR Study", Biol. Chem. Hoppe-Seyler, 374: 403-407, (June 1993)

BZ

Ogata et al.; "Triphosphate Spin-Label Studies of Allosteric Interactions in Hemoglobin", Annals of the New York Academy of Sciences, 222: 56-67, (December 31, 1973)

CA

Oudrhiri et al.; "Gene Transfer by Guanidinium-cholesterol Cationic Lipids Into Airway Epithelial Cells In Vitro and In Vivo", Proc. Natl. Acad. Sci. USA, 94: 1651-1656, (March 1997)

CB

Oudrhiri et al.; "Guanidinium-cholesterol Cationic Lipids : Novel Reagents for Genes Therapy", Biogenic Amines 14(5): 537-552 (1998)

CC

Papassotiriou et al.; "Synthesized Allosteric Effectors of the Hemoglobin Molecule: A Possible Mechanism For Improved Erythrocyte Oxygen Release Capability in Hemoglobinopathy H Disease", Experimental Hematology 26: 922-926, (1998)

CD

Perutz and Poyart; "Bezafibrate Lowers Oxygen Affinity of Haemoglobin", The Lancet, pp. 881-882, (1983)

CE

Perutz F. M.; "Mechanism of Cooperativity and Allosteric Regulation in Proteins", Quarterly Reviews of Biophysics 22 (2): 139-236, (1989)

CF

Pitard et al.; "Structural Characteristics of Supramolecular Assemblies Formed by Guanidinium-cholesterol Reagents for Gene Transfection", Proc. Natl Acad. Sci. USA 96: 2621-2626, (March 1999)

CG

Ruckpaul et al.; "Interaction of Hemoglobin With Ions Allosteric Effects of the Binding of Anion", Biochemica and Biophysica Acta, 236:211-221, (1971)

CH

Tabushi Iwao; "Artificial Allosteric Molecules Especially Focusing Upon Allosteric O<sub>2</sub> Binding Molecules of the Hemoglobin Type", Mol. Struct. Energ. 10:195-218, (1988)

Form PTO-1449

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CI

Teisseire et al.; "Long-term Physiological Effects of Enhanced O<sub>2</sub> Release by Inositol Hexaphosphate-Loaded Erythrocytes", Proc. Natl. Acad. Sci. USA 84:6894-6898, (October 1987)

CJ

Uchida et al.; "Effect of an Allosteric Modifier of Hemoglobin, RSR-4, on Oxygen Affinity and Oxygen Saturation of Hemoglobin in Rabbits", Japanese Journal of Physiology 48: 439-444, (1998)

CK

Vigneron et al.; "Guanidinium-cholesterol Cationic Lipids: Efficient Vectors for the Transfection of Eukaryotic Cells", Proc. Natl. Acad. Sci. USA 93: 9682-9686, (September 1996)

CL

Vigneron Jean-Pierre; "Supramolecular Bioorganic Chemistry: Nucleic Acids Recognition and Synthetic Vectors for Gene Transfer", Molecules 4: 180-203, (1999)

CM

Chuvilin A. N. et al.; "Allosteric Regulators of reversible Hemoglobin Oxygenation", Bioorg. Khim. 16(9): 1157-1176, (1990)

CN

Arnone Arthur; "X-ray Diffraction Study of Binding of 2,3-Diphosphoglycerate to Human Deoxyhaemoglobin", Nature 237: 146-148, (May 19, 1972)

CO

Imai and Yonetani, "Thermodynamical Studies of Oxygen Equilibrium of Hemoglobin", The Journal of Biological Chemistry 250(18): 7093-7098, (1975)

CP

International Search Report Completed on January 2, 2001 and Mailed on February 12, 2001

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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